

CLAIMS

- 5 1. Use of a mutant form of EtxB or CtxB to deliver an agent to a target cell wherein the mutant has GM-1 binding activity; but wherein the mutant has a reduced immunogenic and immunomodulatory activity relative to the wild type form of EtxB or CtxB.
- 10 2. Use according to claim 1 wherein the agent is selected from the group consisting of a peptide or protein of interest (POI); an antigen; an antigenic determinant; an antibody; and a nucleotide sequence of interest (NOI).
- 15 3. Use according to claim 2 wherein the agent may be linked to a membrane translocating or fusogenic peptide.
- 20 4. Use according to claim 3 wherein the membrane translocating or fusogenic peptide may comprise elements of the Pol-loop segment corresponding to a domain in the C-terminal region of HSV-1 polymerase.
- 25 5. Use according to claim 2, 3 or 4 wherein the antigen is selected from the group consisting of a viral antigen, a bacterial antigen, a parasitic antigen; and a tumour associated antigen (TAA).
- 30 6. Use according to any one of claims 1-5 wherein the agent is delivered into a vesicular compartment of the target cell.
7. Use according to any one of claims 1-6 wherein the agent is targeted to the cytosol and/or the nucleus and/or an organelle of the target cell.
8. Use according to any one of the preceding claims wherein the target cell is an antigen presenting cell (APC).

BEST AVAILABLE COPY

9. Use according to any one of the preceding claims wherein the mutant comprises a mutation in the region spanning amino acid residues E51-I58 of the β 4- α 2 loop of CtxB or EtxB.
- 5 10. Use according to claim 9 wherein the mutant comprises a mutation at amino acid residues 51, 56 and/or 57 of the β 4- α 2 loop.
11. Use according to claim 9 or claim 10 wherein the mutant comprises a H57A or H57S mutation.
- 10 12. Use of a mutant according to any one of the preceding claims in the preparation of a medicament to deliver an exogenous peptide into the MHC Class I antigen processing and presentation pathways to elicit a CTL response.
- 15 13. Use according to claim 12 wherein the exogenous peptide is any one of the agents as defined in claim 5.
14. The use of a mutant as defined in any one of claims 1-13 in the preparation of a medicament for separate, simultaneous or combined use to treat a disease or 20 a condition in a subject in need of same.
15. A method of treating a disease or condition in a subject in need of same wherein the method comprises:
 - (i) providing a target cell; and
 - 25 (ii) delivering an agent to the target cell using a mutant as defined in any one of claims 1-13.
16. A method according to claim 15 or the use according to any one of claims 12-14 wherein the disease or condition is a viral infection or a cancer.
- 30 17. A method of delivering an agent using a mutant to a target cell wherein the method comprises:
 - (i) providing a target cell;

- (ii) contacting the cell with the mutant as defined in any one of claims 1-13; and
- (iii) monitoring for the presence of the agent in the target cell.

5 18. A method according to claim 17 wherein the agent is delivered to a vesicular compartment, and/or cytosol and/or nucleus and/or an organelle of the target cell.

10 19. A composition, preferably a pharmaceutical composition, comprising a mutant as defined in any one of claims 1-13 and a pharmaceutically acceptable carrier(s), diluent(s), excipient(s) or adjuvant or any combination thereof.

15 20. A composition comprising a mutant as defined in any one of claims 1-13 which is a vaccine.

21. A kit for delivering an agent to a target cell wherein the kit comprises:

- (i) a mutant as defined in any one of claims 1-13;
- (ii) an agent for delivery to the target cell; and optionally
- (iii) means for detecting the location of the agent in the target cell.

20 22. The use and the method substantially as defined herein and with reference to the accompanying Figures.

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.